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APPLICATION NO.	FI	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION N
10/674,270	09/29/2003		Christopher S. de Voir	117163.00092	3098
21324	7590	11/02/2006		EXAMINER	
HAHN LOE		PARKS, LLP		BROWN JR,	NATHAN H
Suite 300 AKRON, OH 44311-1076				ART UNIT	PAPER NUMBER
				2121	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	10/674,270 Examiner Nathan H. Brown, Jr.	DE VOIR ET AL. Art Unit
Office Action Summary	Nathan H. Brown, Jr.	1
•		1
		2121
The MAILING DATE of this communication apperiod for Reply	ppears on the cover sheet with the c	correspondence address
A SHORTENED STATUTORY PERIOD FOR REP WHICHEVER IS LONGER, FROM THE MAILING I extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory perior. Failure to reply within the set or extended period for reply will, by statu. Any reply received by the Office later than three months after the mail earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICATION .136(a). In no event, however, may a reply be tired will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONE	N. nely filed the mailing date of this communication. ED (35 U.S.C. § 133).
Status		
1) Responsive to communication(s) filed on 10. 2a) This action is FINAL. 2b) Th 3) Since this application is in condition for allow closed in accordance with the practice under	is action is non-final. ance except for formal matters, pro	
Disposition of Claims		•
4) ☐ Claim(s) 1-6 and 8-17 is/are pending in the a 4a) Of the above claim(s) is/are withdr 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-6 and 8-17 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and	awn from consideration.	
Application Papers		
9) The specification is objected to by the Examin 10) The drawing(s) filed on 10 August 2006 is/are Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the 8	e: a)⊠ accepted or b)⊡ objected e drawing(s) be held in abeyance. Se ction is required if the drawing(s) is ob	e 37 CFR 1.85(a). sjected to. See 37 CFR 1.121(d).
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents. 2. Certified copies of the priority documents. 3. Copies of the certified copies of the priority application from the International Bure. * See the attached detailed Office action for a list.	nts have been received. nts have been received in Applicat ority documents have been receiv au (PCT Rule 17.2(a)).	ion No ed in this National Stage
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 10/16/06.	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other:	ate

Examiner's Detailed Office Action

- 1. This Office is responsive to application 10/674,270, filed August 10, 2006.
- 2. Claims 1-6 and 8-17 are pending.
- 3. Claims 1 and 8 are amended.
- 4. Claims 1-18 stand rejected as of the Office Action filed May 11, 2006.

Claims 1-3 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Esteller et al. (US Patent No. 6,594,524).

Claim 1

Esteller teaches an apparatus for the classification of physiological events (col. 5, lines 42-47), comprising:

- a signal input for the input of a physiological signal representing or constituting a physiological event (col. 9, lines 34-36); and
- a classification unit for classifying the physiological signal on the basis of its signal shape (Figs.
- 1, 3, Intelligent Data Processing Unit 200; col. 9, lines 19-28), the classification unit comprising:

a transformation unit which is designed to carry out transformation of the physiological signal in such a way that as the output signal it outputs a number of values representing the physiological signal and based on the transformation (Fig. 4, preprocessing 210 and feature extraction; col. 9,

lines 20-25; col. 20, lines 26-36); and a probabilistic neural network (Fig. 32, col. 36, lines 43-50) which is connected to the transformation unit to receive the values (Fig. 4, analysis/classification 260; col. 10, lines 37-44) and which contains a number of event classes which represent physiological events and which in turn are each represented by a set of comparative values (col. 36, lines 30-40), which probabilistic neural network is adapted on the basis of the comparison of the values with the comparative values to effect an association of the physiological signal represented by the values with one of the event classes (col. 37, lines 10-17).

Claim 2

Esteller teaches the apparatus of claim 1, wherein: the transformation unit is adapted for executing the transformation operation on the basis of wavelets and a transformation rule determining the values to be outputted using the wavelets (col. 28, lines 21-44).

Claim 3

Esteller teaches the apparatus of claim 2, wherein: the comparative values of the probabilistic neural network are based on a transformation procedure in which the same wavelets and the same transformation rule as in the transformation unit are used (Fig. 32, col. 37, lines 10-17; inputs of the neural network come from the outputs of transformation unit, therefore said comparative values are based on the transformation procedure).

Claim 13

Esteller teaches the apparatus of claim 1, wherein: two or more sets of comparative values representing the same event class are present for at least one event class (col. 13, lines 39-44). Claim Rejections • 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-9, 11-12 and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Esteller et al. (US Patent No: 6,594,524) in view of Echauz et al. (US Patent No. 6,678,548).

Claims 4, 11 and 12

Regarding claim 4, Esteller teaches the apparatus of claim 3, wherein the probabilistic neural network further comprises: at least one ascertaining unit for determining association probabilities of the physiological signal with the event classes on the basis of the comparison of the values with the comparative values of the respective event class and for outputting the ascertained association probabilities (Fig. 32, col. 37, lines 11-20);

Esteller does not expressly teach selection unit which is connected to the ascertaining unit for receiving the association probabilities and which is adapted to extract the highest association probability from the association probabilities and to associate the physiological signal with the event class having the highest association probability (it is disclosed in Fig. 32 as competitive layer, but without, a detailed explanation).

However, Echauz teaches selection unit which is connected to the ascertaining unit for receiving the association probabilities and which is adapted to extract the highest association probability from the association probabilities and to associate the physiological signal with the event class having the highest association probability (col. 26, lines 36-39 mention competitive layer as a maximum selector; see also col. 18, lines 53-66).

Esteller and Echauz are analogous art since they are both directed to different aspects of the same invention. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include the details on implementation of a probabilistic neural network from Echauz and combine it with the probabilistic neural network of Esteller. One would be motivated to do it in order to find the details of how the probability of having a seizure is estimated (Esteller, col. 10, lines 47-49). Therefore, it would have been obvious to modify Esteller in view of Echauz by including the details of implemented neural network in the apparatus for predicting seizures.

Claims 11 and 12 are rejected on the same basis as claim 4, having the same limitations but different scope.

Claim 5

Esteller teaches the apparatus of claim 4, wherein: two or more sets of comparative values representing the same event class are present for at least one event class (col. 13, lines 39-44).

Claim 6

Esteller teaches the apparatus of. claim 5, wherein: the ascertaining unit is adapted to determine a plurality of association probabilities for each event class which has two or more sets of comparative values representing the same event class (Fig. 32, T values; col. 37, lines 22-26), and the selection unit is so designed that, for those event classes which have two or more sets of comparative values representing the same event class, it forms average values of the corresponding association probabilities and , upon extraction of the highest association probability uses the average values instead of the individual values (Fig. 32, averaging operation on Ts is shown in circles in the output layer; col. 37, lines 12-20, averaged T1 and T2 form probabilities PI and P2 correspondingly).

Claim 7

Esteller teaches the apparatus of claim 6, further comprising: an adjusting unit for centering the physiological signal in a time window of predetermined window width and for outputting the centered physiological signal to the transformation unit, the adjusting unit connected upstream of the transformation unit (col. 10, lines 5-15; col. 20, lines 26-36).

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Claim 8

Esteller teaches the apparatus of claim 7, wherein: in those event classes which include two or

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more sets of comparative values representing the same event class, the sets of comparative

values correspond to different offsets in the centering of the centered physiological signal (col.

24, lines 62-65; col. 32, lines 62-67).

Claim 9

Esteller teaches an implantable medical device, characterized in that it is provided with an

apparatus for the classification of physiological events as set forth in claim 8 (col. 3, lines 33-

35).

Claim 14

Esteller teaches the apparatus of claim 11, wherein: two or more sets of comparative values

representing the same event class are present for at least one event class (col. 13, lines 39-44).

Claim 15

Esteller teaches the apparatus of claim 12, wherein: two or more sets of comparative values

representing the same event class are present for at least one event class (col. 13, lines 39-44).

Claim 16

Esteller teaches the apparatus 'of claim 14, wherein: the ascertaining unit is adapted to determine

a plurality of association probabilities for each event class which has two or more sets of

comparative values representing the same event class (Fig. 32, T values; col. 37, lines 22-26), and the selection unit is so designed that, for those event classes which have two or more sets of comparative values representing the same event class, it forms average values of the corresponding association probabilities and upon extraction of the highest association' probability uses the average values instead of the individual values (Fig. 32, averaging operation on Ts is shown in circles in the output layer; col. 37, lines 12-20, averaged T1 and T2 form probabilities PI and P2 correspondingly).

Claim 17

Esteller teaches the apparatus of claim 15, wherein: the ascertaining unit is adapted to determine a plurality of association probabilities for each event class which has two or more sets of comparative values representing the same event class (Fig. 32, T values; col. 37, lines 22-26), and the selection unit is so designed that, for those event classes which have two or more sets of comparative values representing the same event class, it forms average, values of the corresponding association probabilities and upon extraction of the highest association probability uses the average values instead of the individual values (Fig. 32, averaging operation on Ts is shown in circles in the output layer; col. 37, lines 12-20, averaged T1 and T2 form probabilities PI and P2 correspondingly).

Claim 18

Esteller teaches the apparatus of claim 6, further comprising: an adjusting unit for centering the physiological signal in a time window of predetermined window width and for outputting the

centered physiological signal to the transformation unit, the adjusting unit being connected upstream of the transformation unit (col. 10, lines 5-15; col. 20, lines 26-36).

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Esteller et al. (US Patent No. 6,594,524) in view of Echauz et al. (US Patent No. 6,678,548), and further in view of Igel et al. (US Patent No. 6,192,273).

Claim 10

Esteller teaches the implantable medical device of claim 9, wherein (col. 3, lines 33-35; disclosed device is capable of doing electric pacing, see col. 14, lines 57-60).

Esteller does not expressly teach that the implantable medical device is in the form of a cardiac pacemaker or defibrillator.

Igel teaches the implantable medical device is in the form of a cardiac pacemaker or defibrillator (Fig. 1, alarm/pacing system 90; col. 3, lines 29-34).

Esteller and Igel are analogous art since they are both implantable devices capable of doing electric pacing. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include the classifier from Esteller and combine it with the implantable device from Igel by using it as a neural network classifier (Igel, col. 7, lines 40-44). Such combination would be reasonable, due to probability neural network being suitable for classification problems and having a straightforward design (Esteller, col. 36, lines 43-46). Therefore, it would have

been obvious to modify Esteller in view of Igel by using the classifier based on a probabilistic neural network in the heart rhythm classifier with an implanted pacemaker.

Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Esteller et al.* (USPN 6,594,524) in view of *Hively et al.* (USPN 6,484,132 B1).

Regarding claim 1. Esteller et al. teach an apparatus for the classification of physiological events (see Abstract, Examiner interprets "forecasting" to be a classification task where the input is a description of some earlier event and the output is the identification of some event that follows (or results from) the earlier event.), comprising:

a signal input for the input of a physiological signal representing or constituting a physiological event (see col. 9, lines 34-36); and

a classification unit (see Fig. 3, item 200 "Intelligent Data Processing Unit") for classifying the physiological signal on the basis of its signal shape (see col. 18, lines 44-50), the classification unit comprising:

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a transformation unit which is designed to carry out transformation of the physiological signal in such a way that as the output signal it outputs a number of values representing the physiological signal and based on the transformation (*see* Fig. 4, preprocessing 210 and feature extraction; col. 9, lines 20-25; col. 20, lines 26-36); and a probabilistic neural network which is connected to the transformation unit to receive the values (see Fig. 32, col. 36, lines 43-50) and which contains a number of event classes which represent physiological events (see Fig. 32, col. 36, lines 30-33) and which in turn are each represented by a set of comparative values, which probabilistic neural network is adapted on the basis of the comparison of the values with the comparative values to effect an association of the physiological signal represented by the values with one of the event classes (*see* col. 36, lines 55-56 and col. 37, lines 27-36, *Examiner interprets "weights used at the hidden layer of the PNN" to be comparative values, which the probabilistic neural network is adapted on.*).

Esteller et al. do not teach an adjusting unit for centering the physiological signal in a time window of predetermined window width and for outputting the centered physiological signal to the transformation unit, the adjusting unit connected upstream of the transformation unit.

However, Hively et al. do teach an adjusting unit (see col. 2, lines 43-46, Examiner interprets the "apparatus including a data collector" to be and adjusting unit.) for centering the physiological signal in a time window of predetermined window width and for outputting the

centered physiological signal to the transformation unit (see col. 14, lines 50-54), the adjusting unit connected upstream of the transformation unit (see col. 2, lines 43-46, Examiner interprets the "apparatus including a data collector" to be and adjusting unit used as a data collector upstream from the transformation unit (see col. 3, lines 1-8).).

Regarding claim 8. Esteller et al. do teach the apparatus of claim 6. Esteller et al. do not teach the apparatus of claim 6, wherein: in those event classes which include two or more sets of comparative values representing the same event class, the sets of comparative values correspond to different offsets in the centering of the centered physiological signal. Hively et al. do teach that, in those event classes which include two or more sets of comparative values representing the same event class (see col. 3, lines 20-22, Examiner interprets a "cutset" to be an event class and the "n-dimensional vector" representations of the g-data to include two or more sets of comparative values representing the same event class.), the sets of comparative values correspond to different offsets in the centering of the centered physiological signal (see col. 3, lines 8-12, "The method connects the flow of each phase-space point into the subsequent phasespace point, as a single connected-phase-space point, which is represented by a discrete 2ndimensional vector.", Examiner interprets the "cutest" to be a collection of connected ndimensional vectors forming a phase-space representation of centered a physiological signal (see col. 14, lines 50-54). Since the collection of n-dimensional vectors form a phase-space (for a process), each vector must have different offsets in the centering of the centered physiological signal (or else the phase-space would, simply, be a point attractor, i.e., no process).).

It would have been obvious at the time the invention was made to persons having ordinary skill in the art to combine *Esteller et al.* with *Hively et al.* to apply a reliable technique for measuring condition change in nonlinear physiological data (e.g., brain waves).

7. Claims 4, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Esteller* et al. (USPN 6,594,524) in view of *Echauz et al.* (USPN 6,678,548).

Regarding claims 4, 11, and 12. *Esteller et al.* teaches the apparatus of claim 3, wherein the probabilistic neural network further comprises: at least one ascertaining unit for determining association probabilities of the physiological signal with the event classes on the basis of the comparison of the values with the comparative values of the respective event class and for outputting the ascertained association probabilities (*see* Fig. 32, col. 37, lines 11-20). *Esteller et al.* does not expressly teach selection unit which is connected to the ascertaining unit for receiving the association probabilities and which is adapted to extract the highest association probability from the association probability (it is disclosed in Fig. 32 as competitive layer, but without a detailed explanation). However, *Echauz et al.* teaches selection unit which is connected to the ascertaining unit for receiving the association probabilities and which is adapted to extract the highest association probability from the association probabilities and to associate the physiological signal with the event class having the highest association probability

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(see col. 26, lines 36-39 mention competitive layer as a maximum selector; see also col. 18, lines 53-66). It would have been obvious to a person of ordinary skill in the art at the time of the invention to include the details on implementation of a probabilistic neural network from Echauz et al. and combine it with the probabilistic neural network of Esteller et al. in order to find the details of how the probability of having a seizure is estimated.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Esteller et al.* (US Patent No. 6,594,524) in view of *Echauz et al.* (US Patent No. 6,678,548), and further in view of *Igel et al.* (US Patent No. 6,192,273).

Regarding claim 10. Esteller et al. teach the implantable medical device of claim 9 (see Abstract). Esteller et al. and Echauz et al. do not teach that the implantable medical device is in the form of a cardiac pacemaker or defibrillator. Igel et al. teach that the implantable medical device is in the form of a cardiac pacemaker or defibrillator (see Fig. 1, col. 3, lines 24-34, Examiner interprets "device 10 may optionally comprise a therapy system 70 for delivering electrical shock or pacing impulses" to mean an implantable medical device is in the form of a cardiac pacemaker or defibrillator.). It would have been obvious to a person of ordinary skill in the art, at the time of the invention, to combine the probabilistic neural network classifier from Esteller et al. and Echauz et al. with the implantable device of Igel et al. to obtain a neural network classifier for "adaptively sampling a cardiac electrical signal for use in a heart rhythm classifier" (see Igel et al., col. 2, lines 38-40).

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9. Claims 2, 3, 5, 6, 9, and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Esteller et al.*

Regarding claim 2. *Esteller et al.* teaches the apparatus of claim 1, wherein: the transformation unit is adapted for executing the transformation operation on the basis of wavelets and a transformation rule determining the values to be outputted using the wavelets (*see* col. 28, lines 21-44).

Regarding claim 3. *Esteller et al.* teaches the apparatus of claim 2, wherein: the comparative values of the probabilistic neural network are based on a transformation procedure in which the same wavelets and the same transformation rule as in the transformation unit are used (*see* Fig. 32, col. 37, lines 10-17; inputs of the neural network come from the outputs of transformation unit, therefore said comparative values are based on the transformation procedure).

Regarding claim 5. Esteller et al. teaches the apparatus of claim 4, wherein: two or more sets of comparative values representing the same event class are present for at least one event class (see col. 13, lines 39-44).

Regarding claim 6. Esteller et al. teaches the apparatus of. claim 5, wherein: the ascertaining unit is adapted to determine a plurality of association probabilities for each event class which has two or more sets of comparative values representing the same event class (see Fig. 32, T values; col. 37, lines 22-26), and the selection unit is so designed that, for those event classes which have

two or more sets of comparative values representing the same event class, it forms average values of the corresponding association probabilities and, upon extraction of the highest association probability uses the average values instead of the individual values (*see* Fig. 32, averaging operation on Ts is shown in circles in the output layer; col. 37, lines 12-20, averaged T1 and T2 form probabilities PI and P2 correspondingly).

Regarding claim 9. Esteller et al. teaches an implantable medical device characterized in that it is provided with an apparatus for the classification of physiological events as set forth in claim 8 (see Abstract).

Regarding claim 14. Esteller et al. teaches the apparatus of claim 11, wherein: two or more sets of comparative values representing the same event class are present for at least one event class (see col. 13, lines 32-36, Examiner interprets "electrical, magnetic, chemical, sensorial or cognitive stimulation variables" to be comparative values representing the same event class are present for at least one event class.).

Regarding claim 15. Esteller et al. teaches the apparatus of claim 12, wherein: two or more sets of comparative values representing the same event class are present for at least one event class (see above).

Regarding claim 16. Esteller et al. teaches the apparatus of claim 14, wherein: the ascertaining unit is adapted to determine a plurality of association probabilities for each event class which has

two or more sets of comparative values representing the same event class (see Fig. 32, col. 37, lines 21-26, Examiner interprets the entries of Matrix T to determine a plurality of association probabilities for each event class.), and the selection unit is so designed that, for those event classes which have two or more sets of comparative values representing the same event class, it forms average values of the corresponding association probabilities (see Fig. 32, Examiner interprets the output units P_1 and P_2 to form the average of T_{1j} and T_{2j} , respectively, where each T_{ij} is "the probability that the input signals belong to the pre-seizure/seizure class".) and upon extraction of the highest association probability uses the average values instead of the individual values (see Fig. 32, Examiner interprets the units of the "Competitive Layer" to extract the highest association probability by picking one of P_1 or P_2 which use the average of T_{1j} and T_{2j} , respectively.).

Regarding claim 17. Esteller et al. teaches the apparatus of claim 15, wherein: the ascertaining unit is adapted to determine a plurality of association probabilities for each event class which has two or more sets of comparative values representing the same event class (see Fig. 32, col. 37, lines 22-26, Examiner interprets the entries of Matrix T to comprise two or more sets of comparative values representing the same event class (e.g., T11 and T21 emanate from the same hidden unit, which represents a class of pre-seizure data).), and the selection unit is so designed that, for those event classes which have two or more sets of comparative values representing the same event class, it forms average, values of the corresponding association probabilities and upon extraction of the highest association probability uses the average values instead of the individual values (see Fig. 32, Examiner interprets the units of the "Competitive Layer" to

extract the highest association probability by picking one of P_1 or P_2 which use the average of T_{1j} and T_{2j} , respectively.).

Response to Arguments

Applicant's arguments with respect to claims 1-18 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan H. Brown, Jr. whose telephone number is 571-272-8632. The examiner can normally be reached on M-F 0830-1700. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Knight can be reached on 571-272-3687. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Anthony Knight

Supervisory Patent Examiner

Tech Center 2100

Nathan H. Brown, Jr. October 20, 2006